REMARKS

This application has been amended in a manner that is believed to place it for allowance at the time of the next Official Action.

Claims 80, 95, 99, and 100 are amended. Claims 101-127 are new. Claim 74 and 79 are canceled. Claims 75-78 and 80-127 remain pending in the present application.

Support for the amended and new claims may be found generally throughout the specification, particularly in examples 7 and 9, page 38, lines 10-17 and page 45, lines 23-27.

The Official Action rejected claim 79 under 35 USC §112 for depending from a canceled claim. Claim 79 is canceled.

The Official Action rejected claims 74-77, 80-87, 89, 90 and 95-100 under 35 USC §102(b) as allegedly being anticipated by HUTCHINSON 5,366,734. Applicants respectfully traverse the rejection.

HUTCHINSON discloses a composition for implants comprising up to and including 50% of an active ingredient.

The independent claims 80, 95, 99, and 100 recite a solid or semisolid delayed release formulation in which the quantity of active principle is above 50% and less than or equal to 80%.

As HUTCHINSON fails to disclose any quantity of active ingredient above 50% of the composition, HUTCHINSON does not anticipate the presently claimed invention.

Therefore, applicants respectfully request that the anticipation rejection be withdrawn.

Claims 74-90 and 95-100 were rejected under 35 USC §103(a) as allegedly being unpatentable over HUTCHINSON in view of RAMCHANDANI. Applicants respectfully traverse the rejection.

HUTCHINSON discloses a composition for implants comprising up to and including 50% of an active ingredient. HUTCHINSON fails to disclose or suggest a quantity of active principle above 50% and less or equal to 80% as recited in the independent claims 80, 95, 99 and 100 of the claimed invention.

The Official Action offers RAMCHANDANI for teaching monophasic drug loading levels of greater than or equal to 35%. The Official Action concludes that it would have been obvious to incorporate drug loading levels of greater than or equal to 35% into HUTCHINSON's composition because it would allow more control of variables to create a continuous release of active ingredients at a higher dosage.

However, contrary to the assertion made in the Official Action, RAMCHANDANI fails to disclose or suggest drug loading above 50%. RAMCHANDANI describes the production of microcapsules "containing 10%, 20%, 35% and 50% w/w drug loading" (page 169, first paragraph, right-hand column). Implants made therefrom are

also disclosed with the same drug loading as the microcapsules used for their preparation (Section 2.6, page 169). RAMCHANDANI then concludes that the release of ciprofloxacin HCl from the implants was biphasic at ≤20% w/w drug loading and the release was monophasic at drug loading levels ≥35% w/w. Thus, at best, RAMCHANDANI suggests ≥35% w/w corresponds to 35% and 50% drug loading.

Therefore, none of the cited publications disclose implants having a drug loading above (strictly) 50% and less or equal to 80%.

Moreover, there is no motivation in either document to go beyond the threshold of 50%, where the drug is the major component. Usually the drug is the minor component dispersed inside the polymer matrix. Thus, even if one were to combine HUTCHINSON and RAMCHANDANI, at best the combination teaches 35-50% drug loadings.

Notwithstanding the fact that the proposed combination does not teach the claimed invention, the claimed invention is nevertheless non-obvious because of the unexpected results of the more than 50% active principle.

It cannot be derived from the publications that a solid formulation wherein the peptidic or protein molecule is the main component, forms the matrix and leads to the specific release profile as disclosed by the present invention. The publications do not suggest that a formulation having more than 50% peptidic

or proteic active principle would have those different properties versus formulations having less than 50% of peptidic or proteic active principle, as it comes from the examples of the present application (e.g. examples 4 and 10). The claimed solution leads to different liberation patterns that were not expectable.

It must be emphasized that the formulation with high content of active principle (those presently claimed) were specifically designed for peptidic or proteic molecules. (Please refer to page 40, lines 18-19, which specifically refer to implants having more than 50% drug loading). This embodiment is said to be very advantageous for fragile molecules such as proteins and peptides.

As the proposed combination fails to teach the composition of independent claims 80, 95, 99, and 100, and the claimed composition has unexpected results, the proposed combination of HUTCHINSON and RAMCHANDANI does not render obvious claims 80, 95, 99, and 100. Claims 75-78, 81-94, 96-98 and 101-127 are dependent claims and are also non-obvious.

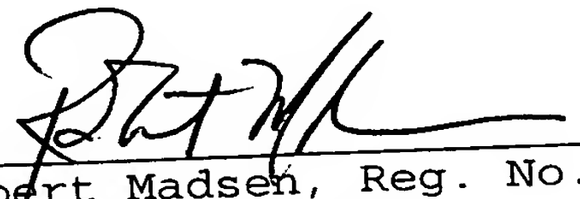
Therefore, applicants respectfully request that the obviousness rejection be withdrawn.

Applicants believe that the application is in condition for allowance at the time of the next Official Action. Allowance and passage to issue on that basis is respectfully requested.

The Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 25-0120 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17.

Respectfully submitted,

YOUNG & THOMPSON



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